REMARKS

FORMAL MATTERS:

Claims 1-13 and 19 are pending after entry of the amendments set forth herein.

The amendment to claim 7 is formal in nature and has been made in order to provide for proper antecedent basis for the term "formulation" within the independent claim 19. This would not add new issues or require further searching and as such is a proper amendment under 37 C.F.R. §1.116. Accordingly, entry of the amendment is respectfully requested.

REJECTIONS UNDER §112, ¶2

Claims 7-13 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter.

The rejection appears to be correct. Clearly, applicants have amended claim 7 to include the term "formulation" which does appear within claim 19 thereby provide a proper antecedent basis for this term within claim 7 and thereby overcoming the rejection.

REJECTIONS UNDER §102

Claims 14-18 are rejected under 35 U.S.C. §102(b) as being anticipated by Butrous et al.

Although the rejection is traversed as applied applicants wish to expedite prosecution of the application. Accordingly, claims 14-18 have been canceled thereby rendering the rejection moot.

REJECTIONS UNDER §103(A)

Claims 1, 5, 7-13 and 19 are rejected under 35 U.S.C. §103(a) as being unpatentable over Butrous et al. in view of Ellis et al.

Butrous et al. teach the use of compounds referred to as PDE5 inhibitors for the treatment of pulmonary hypertension. Butrous et al. do not teach the use of such compounds for the treatment of erectile dysfunction. Applicants also recognize that Butrous et al. teach the rapid onset of PDE5 inhibitors for the treatment of pulmonary hypertension. However, applicants point out that the rapid onset here is where the drug is delivered directly to the target organ, i.e. the PDE5 inhibitors are delivered directly to the surface of the lung being treated. Butrous et al. does not teach that PDE5

inhibitors would be expected to have rapid onset when administered for another purpose such as for the treatment of erectile dysfunction where the medication is not applied directly to the surface of the organ being treated. Specifically, the rapid onset shown by Butrous et al. would not be expected in a situation where the drug is not being directly delivered to the organ being treated such as for the treatment of erectile dysfunction.

To further support the rejection Ellis et al. has been cited for its disclosure for sildenafil for the treatment of erectile dysfunction. However, Ellis et al. do not teach pulmonary delivery of sildenafil and specifically do not teach that such pulmonary delivery might result in rapid onset for the treatment of erectile dysfunction.

When using applicants' disclosure as a blueprint for the method of the invention the combination of the references may appear obvious. However, in the absence of applicants' teachings nothing within the references suggest that it would be useful to treat erectile dysfunction by inhaling a PDE5 inhibitor into the lung in order to target and rapidly treat erectile dysfunction.

Rapid onset has great utility in terms of the treatment of erectile dysfunction. A substantial factor regarding whether or not a sex act will be performed depends on the mental state of the individuals. That mental state can change rapidly over a relatively short period of time. Utilizing the present invention the physiological aspects (erectile dysfunction) which would prevent the performance of the sex act are quickly removed by rapid treatment of the erectile dysfunction. **The references as taken alone or in combination do not recognize this benefit and as such do not teach towards rapid treatment of erectile dysfunction by the inhalation of sildenafil.** There are vast amounts of existing information to indicate that mood or mental state of the individuals involved is critical to having an enjoyable sexual experience. If the erectile dysfunction cannot be dealt with quickly when the mood and circumstances are right the administration of a treatment which takes longer may be completely futile. This is true because once the mood and circumstances have passed the sex act will not take place even though the physiological issue (erectile dysfunction) has been corrected. In view of such applicants invention provides an improved unexpected result which is not taught within the references and not obvious in view of the references. Had the references recognized this rapid onset result such would have been taught in that a clear advantage exists which would be readily recognized by many individuals who experience or who are involved in treating erectile dysfunction. In view of such the rejection should be reconsidered and withdrawn.

Claims 2-4 and 6 are rejected under 35 U.S.C. §103(a) as being unpatentable over Butrous et al. in view of Ellis et al. as applied to claims 1, 5, 7-13 and 19 above.

This rejection is also traversed for the reasons indicated above. The additional citation of the drug information handbook adds nothing to the strength of the rejection. There is no recognition that the aerosolized delivery of sildenafil to treat erectile dysfunction will provide rapid onset and provide the desired results within the desired circumstances and mood. In view of such the rejection should be reconsidered and withdrawn.

Still further, it is applicants' position that the references have been combined together by picking and choosing individual features of one reference which discloses only those limited parts necessary to support the rejection without a full appreciation of what the reference fairly suggest to one of ordinary skill in the art. Here, the combination of references do not fairly teach towards applicants claimed method of aerosolized delivery of sildenafil to obtain the desired fast acting affect with respect to the treatment of erectile dysfunction. In view of such the rejection should be reconsidered and withdrawn.

CONCLUSION

Claim 7 has been amended to overcome the 35 U.S.C. §112 rejection. The 35 U.S.C. §102 rejections have been rendered moot by the cancellation of the claims 14-18. The 35 U.S.C. §103 rejections are traversed in that the references as taken alone or in combination do not recognize the improved fast acting effect on the treatment of erectile dysfunction by the aerosolized administration of sildenafil. Such fast acting effect provides substantial improved results which are not obvious from a reference such as Butrous et al. which teaches a fast acting effect when the drug is administered directly to the organ being treated. In view of such the rejections should all be reconsidered and withdrawn.

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

Atty Dkt. No.: AERX-080CIP2
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The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number AERX-080CIP2.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 6/Oct/06

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